

NYSTATIN - nystatin cream
E. FOUGERA & CO.

Rx only

DESCRIPTION

Nystatin Cream contains the antifungal antibiotic Nystatin at a concentration of 100,000 units per gram in an aqueous, vanishing cream base containing Polysorbate 60, Aluminum Hydroxide Compressed Gel, Titanium Dioxide, Glyceryl Monostearate, Polyethylene Glycol 400 Monostearate, Simethicone, Sorbic Acid, Propylene Glycol, Ethylenediamine, Polyoxyethylene Fatty Alcohol Ether, Sorbitol Solution, Methylparaben, Propylparaben, Hydrochloric Acid, White Petrolatum, and Purified Water.

ACTIONS

Nystatin is an antifungal antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. It probably acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin is a polyene antibiotic of undetermined structural formula that is obtained from *Streptomyces noursei*, and is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous, oral and intestinal infections caused by *Candida* [Monilia]*albicans* and other *Candida* species. It exhibits no appreciable activity against bacteria.

Nystatin provides specific therapy for all localized forms of candidiasis. Symptomatic relief is rapid, often occurring within 24 to 72 hours after the initiation of treatment. Cure is effected both clinically and mycologically in most cases of localized candidiasis.

INDICATIONS

Nystatin topical preparations are indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* [Monilia]*albicans* and other *Candida* species.

CONTRAINDICATIONS

Nystatin topical preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

PRECAUTIONS

Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.

ADVERSE REACTIONS

Nystatin is virtually non-toxic and nonsensitizing and is well tolerated by all age groups including debilitated infants, even on prolonged administration. If irritation on topical application should occur, discontinue medication.

DOSAGE AND ADMINISTRATION

Nystatin cream should be applied liberally to affected area twice daily or as indicated by a physician. The preparation does not stain skin or mucous membranes and provides a simple, convenient means of treatment.

HOW SUPPLIED

Nystatin Cream is available as follows:

NDC 0168-0054-15 15 gram tube

NDC 0168-0054-30 30 gram tube

Store at controlled room temperature 15°-30°C (59°-86°F).

E. FOUGERA & CO.

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